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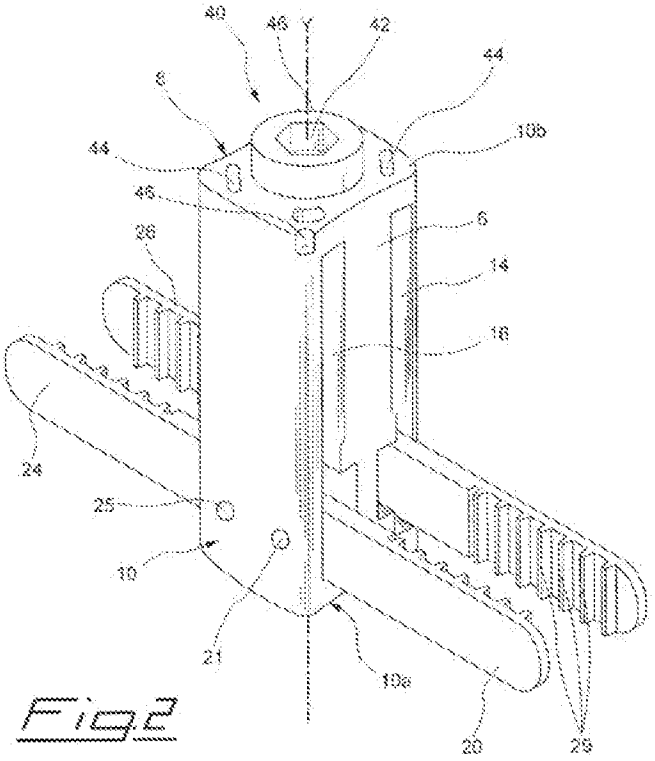


Fig2

(57) Abstract: Percutaneous interspinous process spacer comprising a spacer member (10) comprising: rotatable arms (20, 22; 24,26) connected to a distal end of the spacer, configured to assume a collapsed configuration and an extended configuration; actuation means (30, 32, 34) to effect transition from said collapsed configuration to said extended configuration, and vice- versa; engaging means (40) disposed at a proximal portion (10b) of the spacer (10), configured to engage said actuation means (30, 32, 34) with an instrument (90) for implanting said interspinous process spacer. Described are also a method, an instrument and a kit for implanting the interspinous process spacer in a patient's body.

WO 2009/083583 A1

PERCUTANEOUS INTERSPINOUS PROCESS SPACER

DESCRIPTION

The invention relates to a percutaneous interspinous process spacer, and more particularly, to a percutaneous interspinous process spacer for implantation, for example, between posterius adjacent spinous processes of the spine for the treatment of degenerative spinal conditions.

Spinal stenosis, degenerative disc disease and other degenerative cause compression of the spinal cord and nerve impingement. They can cause pain, restricted activity and other disorders. Because spinal stenosis and degenerative disc disease are progressive diseases, surgery may eventually be required to address the source of pressure causing the pain. Such known surgical procedures can involve surgical decompression to relieve pressure on the spinal cord or spinal nerve by widening the spinal canal to create more space.

Minimally-invasive procedures have been developed to provide access to the space between adjacent spinous processes such that open surgery is not required. Such known procedures include, for example, percutaneously inserting a spacer between adjacent spinous processes. Such spacers typically include a retention portion configured to limit movement of the spacer and prevent the spacer from sliding out from between the spinous processes.

WO 2007/089905 A2 discloses interspinous process spacers or implants of a general rectangular shape with a nose having a tapered shape and a rounded distal tip. Depressions extending laterally across the upper and/or lower face are designed to receive a spinous process while providing minimized bone contact to reduce or eliminate bone fusion. Such spacers are to be inserted laterally into the interspinous space through a small, posterior incision, thereby allowing the preservation of the supraspinous ligament. This latter, however, varies greatly in form from one spinal region to another. In the cervical region it contains an abundance of elastic fibres, whilst in the lumbar region it is weaker and may even be absent. Therefore, lateral insertion to preserve the supraspinous ligament requires penetration through relatively large portions of tissues, fascial layers and muscles of the back, with blood loss and increased chances of complications. Also, penetration time in case of lateral insertion is typically relatively long and requires continuous fluoroscopic guidance with associated relatively large X-ray exposure.

WO 2006/089085 A2 discloses percutaneous spinal implants including an elongate member having proximal and distal portions configured to be expanded after implantation, and a non-expanding central portion configured to engage adjacent spinous processes. In the cited document and in the present description the word "proximal" and "distal" refer to direction closer to and away from, respectively, an operator (e.g. surgeon) who would insert the

medical device into the patient, with the tip-end (i.e., distal end) of the device inserted in a patient's body first. Thus, for example, the implant end first inserted inside the patient's body would be the distal end of the implant, while the implant end to last enter the patient's body would be the proximal end of the implant.

Spinal implants of WO 2006/089085 A2 are to be inserted laterally into a patient's body, like interspinous process spacers or implants of WO 2007/089905 A2. Thus, they suffer the same drawbacks as those described with respect to WO 2007/089905 A2.

US 2006/0264938 A1 discloses an interspinous process implant having deployable wings that are hinged to a distal end of a main body so that in a collapsed configuration they form a distraction guide at the distal end of the main body. The tip of the distraction guide formed by the wings pierces an opening in an interspinous ligament and between interspinous processes when inserted laterally by a physician. Once the implant is positioned between spinous processes the wings can be rotated to a second configuration in which abut at least one of the spinous processes. Also this spinous implant is to be inserted laterally, as shown clearly by Fig. 3b of US 2006/0264938, in which both wings 312, 314 are positioned at one side of spinous process 2, 4 with respect to a sagittal plane.

US 2006/0084988 A1 discloses systems and methods for posterior dynamic stabilization of the spine. In one embodiment (Fig. 25A, B, C) a spacer device has a tubular or cylindrical configuration with side blocks aligned with the longitudinal axis of a core member. The side blocks are expandable by means of linkages to a fully deployed state. Such spacer device is to be inserted laterally to one side of the spinal motion segment to be treated.

WO 2007/075788 A2 discloses systems and methods for posterior dynamic stabilization of the spine. In one embodiment (Fig. 32A, B, C) a spacer device has two extension pairs positioned at a proximal end of a hub and two extension pairs positioned at a distal end of a hub. In an undeployed state the latter are folded in a distal direction and the former are folded in a proximal direction. In other embodiments (Fig. 33A, B, C; Figs. 41; 43; 44; 45) the spacer device has arm pairs hinged to a distal end and folded in a distal direction in an undeployed state. When inserted percutaneously by operating in the sagittal plane, the arms in the unfolded state penetrate into the tissues surrounding the spine and create a cavity in a region beyond the point at which the arms engage the spinous processes after deployement. Such cavity is enlarged during deployment to engage the spinous processes by the rotation of the arm backwardly, namely toward the proximal end of the spacer. The creation of a cavity in the region beyond the point at which the arms engage the spinous processes is undesirable since it may cause an anterior shift of the spacer with associated risk of damage of the nervous

structures in the spinal canal. Also, the arms and parts of the actuation mechanism are fully exposed to contact with tissues removed during implantation and deployment, resulting in possible adhesion of parts of such tissues to the arms. This may alter the engagement of the arms with the spinous processes and/or the functioning of the actuation mechnasim.

Thus, a need exists for improvements in the treatment of spinal conditions such as spinal stenosis , degenerative disc disease and other degenerative conditions.

In the present description reference is made also to the following imaginary planes of the human body:

- Sagittal plane: it is an imaginary anatomical plane that travels from the top to the bottom of the body, dividing the body into left and right portions of the same size passing through midline structure, as shown in Fig. 5. Planes that are parallel to the sagittal plane but do not pass through the midline are known as parasagittal planes.
- Coronal (or frontal) plane: it is an imaginary anatomical plane that divides the body into dorsal and ventral (back and front) portions. It is a plane perpendicular to the sagittal plane, as shown in Fig. 5.
- Transverse (or horizontal) plane: it is an imaginary anatomical plane that divides the body into cranial and caudal (top and bottom) portions. It is a plane perpendicular to both the sagittal and coronal planes.

In a first aspect, the present invention relates to a percutaneous interspinous process spacer comprising a spacer member comprising:

- rotatable arms configured to assume a collapsed configuration and an extended configuration;
- actuation means to effect transition from said collapsed configuration to said extended configuration of said arms, and vice-versa;
- engaging means disposed at a proximal portion of said spacer member, configured to operate said actuation means with an instrument for implanting said interspinous process spacer;

characterized in that said rotatable arms are connected to a distal portion of said spacer member and in said collapsed configuration are folded in a proximal direction;

whereby said arms are extended by rotation in a distal direction and in said extended configuration operatively engage spinous process of a patient to limit movement thereof.

In an other aspect, the present invention relates to a percutaneous interspinous process spacer as described above, wherein said rotatable arms are hinged at a distal portion of said spacer member. Preferably, said arms comprise a pair of upper arms and a pair of lower arms, both

hinged at a distal portion of said spacer member, said upper arms and lower arms being defined with respect to the position of the spacer between an upper and a lower spinous process.

In an other aspect, the present invention relates to a percutaneous interspinous process spacer as described above, wherein the arms of each of said pair of arms are symmetrically disposed with respect to a longitudinal central plane of said spacer member corresponding to the sagittal plane of a patient's body after implantation.

In an other aspect, the present invention relates to a method of implanting a percutaneous interspinous process spacer as described above into a body, wherein said method comprises the steps of:

a) percutaneously providing a cavity between the anterior and posterior portions of two adiacent spinous processes of a body, said cavity being provided by operating substantially in the sagittal plane;

b) percutaneously inserting an interspinous process spacer in a collapsed configuration, said insertion being performed by operating substantially in the sagittal plane;

c) percutaneously effecting said transition from said collapsed configuration to said extended configuration by engaging means disposed at a proximal portion of said spacer, configured to engage an instrument for implanting said interspinous process spacer, said instrument being engaged and operated substantially in the sagittal plane, said transition comprising a rotation of the arms of said spacer in a distal direction;

whereby said spacer in said extended configuration operatively engage spinous process of a patient to limit movement thereof.

In a further aspect, the present invention relates to an instrument for implanting a percutaneous interspinous process spacer as described above into a patient's body, characterized by comprising means for engaging and supporting said percutaneous interspinous process spacer at the proximal end thereof, and means to effect transition from said collapsed configuration to an extended configuration of said spacer member.

In a still further aspect, the present invention relates to a kit comprising a percutaneous interspinous process spacer, an instrument for implanting a percutaneous interspinous process spacer, and one or more tools used in said method.

The invention is better understood by reference to the following drawings, which are merely exemplary to illustrate the invention.

Fig. 1 is a schematic perspective view of a percutaneous interspinous process spacer according to a first embodiment of the invention in a collapsed configuration;

Fig. 2 is a schematic view of the spacer of Fig. 1 in an extended configuration;

Fig. 3 is a schematic partially broken view of the spacer of Fig. 1 and 2;

Fig. 4 is a schematic perspective view of a percutaneous interspinous process spacer according to a second embodiment of the invention in an extended configuration;

Fig. 5 is a schematic perspective view of the spacer according to the invention in a collapsed configuration between adjacent interspinous processes in a patient's body;

Fig. 6 is a schematic perspective view of the spacer of Fig. 5 in an extended configuration between adjacent interspinous processes in a patient's body;

Fig. 7 is a schematic enlarged perspective view of the spacer of Fig. 6 between adjacent interspinous processes in a patient's body;

Fig. 8-14 show schematically the steps of a method of implanting a percutaneous interspinous process spacer according to the invention;

Fig. 15-16 are perspective partial views of an instrument to implant a percutaneous interspinous process spacer according to an embodiment of the invention; and

Fig. 17 is a partial sectional view of the instrument of Figs. 15-16.

With reference to Figures 1-3, a percutaneous interspinous process spacer according to an embodiment of the invention comprises a spacer member designated generally with 10. Spacer member 10 has substantially the shape of a parallelepiped with rounded corners and with two opposed faces 6, 8 that are slightly concave. Of course other embodiments are possible, for example with a spacer member having a cylindrical shape, or other suitable shapes. With reference to implanting spacer member 10 between adjacent spinous processes of a human body, bottom 10a is the distal end and top 10b is the proximal end.

As shown in Fig. 2 and 3, the spacer member 10 comprises two pair of arms 20, 22 and 24, 26, each pair being hinged at the distal portion 10a of member 10 by means of pins 21, 25 rotatably mounted in corresponding holes of member 10. More particularly, arms 20 and 22 are fixed to pin 21, so that any rotation of pin 21 is transmitted to arms 20, 22. In the same manner, arms 24 and 26 are fixed to pin 25, so that any rotation of pin 25 is transmitted to arms 24, 26.

The body of spacer member 10 is hollow, and in the internal cavity are hosted actuation means to effect rotation of arms 20, 22 and 24, 26. Such means comprise a rod 32 provided with a threaded upper portion 34 ("upper" meaning the portion toward the proximal end of spacer 10) engaging an internal thread of a nut 36 rotatably mounted within the body of spacer member 10. Nut 36 is prevented from sliding within the body of spacer member 10 by an upper rib 36a hosted in a corresponding seat in the inner wall 11 of member 10. Threaded

nut 36 is rigidly connected to engaging means 40 located at the proximal end 10b of member 10. Engaging means 40 comprise a socket head screw 42 designed to engage a setscrew wrench (not shown), whereby internally threaded nut 36 is rotated. Engaging means 40 comprise also a plurality of slits 44,46 on the proximal end of spacer 10. Slits 44,46 are designed to engage corresponding projections of an instrument for implanting the interspinous process spacer, as it will be described in the following.

The lower portion of rod 32 ("lower" meaning the portion toward the distal end of spacer 10) is a double rack 30, 33, that engages gear wheels 23, 27 rigidly mounted on pins 21, 25, respectively.

Therefore, rotation of engaging means 40 causes rotation of nut 36, which causes a linear movement of rod 32 in the upper or lower direction within spacer member 10, depending on the direction of rotation of nut 36. Linear movement of rod 32 and of double rack 30, 33 causes rotation of gear wheels 23, 27, and of arms 20, 22, 24, 26.

With reference to Fig. 1 and 2, the two pairs of arms 20, 22 and 24, 26 are configured to assume a collapsed configuration and an extended configuration.

The collapsed configuration corresponds to an undeployed state. In such state the two pairs of arms are folded in a proximal direction, namely the tips of the arms are close to the proximal end of the spacer.

The extended configuration corresponds to a deployed state. In such state the two pairs of arms have been rotated of about 90° in a distal direction, namely the tips of the arms have been moved away from the proximal end of the spacer and the arms are oriented perpendicularly to the longitudinal axis Y of the spacer.

In the embodiment of Figs. 1, 2 and 3 the collapsed configuration is the configuration in which the two pairs of arms are contained in the internal cavity of hollow spacer member 10, as shown in Fig. 1. The extended configuration is the configuration in which the two pairs of arms project from the internal cavity of hollow spacer member 10, as shown in Fig. 2, to assume a configuration substantially perpendicular to the vertical, or longitudinal, axis Y, where the term "vertical" refers to the disposition of spacer member 10 in Figg. 1-3, not in a patient's body. Transition from a collapsed configuration to an extended configuration is possible since arms 20, 22, 24, 26 pass through vertical slits 14, 16 provided in the opposite faces 6, 8, of spacer member 10. In the fully deployed state arms 20, 22, 24, 26 abut against the distal end 10a of the spacer, which limits any further rotation of the arms. The first pair of arms 20, 22 and the second pair of arms 24, 26 are symmetrically disposed with respect to a central plane containing the longitudinal axis Y of the spacer member 10, and said central

plane coincides substantially with the sagittal plane (S) of a patient's body (Fig.6) after implantation of the spacer member, as it is described below.

The internal side of each arm 20, 22, 24, 26 has a rough or shagreened surface and/or is provided with teeth or projections 29 (Fig. 2), to increase gripping to the spinous processes after spacer 10 has been implanted in the target position.

Fig. 4 shows another embodiment of the spacer according to the invention, in which arms 20',22' and 24',26' are mounted externally with respect to the body of the spacer, on pins 21',25' that project from said body. In the collapsed configuration (not shown) arms 20',22', 24',26' rest on the opposed external sides of spacer 10, which can be formed without vertical slits 14,16. Means to prevent further rotation of the arms beyond about 90° from the longitudinal axis of the spacer are preferably provided. Such means may be in the form of abutment means like shown in Figs. 1 and 2, or by other suitable means, including double rack 30, 33 and gear wheels 23, 27, designed in such a way that the extent of rotation of arms 20, 22, 24, 26 does not exceed a desired angle.

Fig. 5 and 6 show a posterolateral side of human spine with a percutaneous interspinous process spacer inserted between the fourth and fifth vertebra L4, L5. More precisely, percutaneous interspinous process spacer 10 is inserted between spinous processes 51 and 52 of vertebra L4, L5, respectively. Fig. 7 is an enlarged side view of the spacer 10 implanted at a target position between two adjacent spinous processes 51, 52. Fig. 6 shows the sagittal plane S extending through the midline of a patient's body, and the coronal plane C perpendicular to the sagittal plane.

After interspinous process spacer 10 has been inserted percutaneously in the collapsed configuration between upper spinous process 52 and lower spinous process 51 (Fig. 5), transition to the extended configuration is effected by rotating the arms toward the distal end of the spacer. Fig. 6 and 7 show spacer 10 in the extended configuration, with longitudinal axis Y of the spacer lying in the sagittal plane S and with arms 22, 26 (and corresponding arms 20, 24, not shown) laying in parasagittal planes (not shown) and engaging spinous processes 51, 52, to prevent movement of spacer 10 from the desired target position.

The method of implanting a percutaneous interspinous process spacer as described above into a body, according to the invention, comprises the steps of:

a) providing a cavity between the anterior and posterior portions of two adiacent spinous processes of a body by operating percutaneously and substantially in the sagittal plane;

b) inserting in the cavity an interspinous process spacer with rotatable arms in a collapsed configuration, said insertion being performed by operating percutaneously and

substantially in the sagittal plane;

c) effecting a transition from the collapsed configuration to an extended configuration of said arms by an instrument engaging means disposed at a proximal end of said spacer, said instrument being operated percutaneously and substantially in the sagittal plane, so that said arms in the extended configuration operatively engage adjacent spinous processes of a patient to limit movement of the spacer.

The steps of the method of implanting are described in more detail with reference to Fig. 5, 6, 7, and 8-14:

a1) After having anesthetized the patient, typically by local anesthesia, the surgeon inserts a discal needle 70 (Fig. 8) between two spinous processes 51, 52, under fluoroscopic guidance, by penetrating from the back along the sagittal plane of the patient, as shown by arrow A of Figs. 6 and 8;

a2) A "Kirschner Wire" 72, or K-wire, is then introduced (Fig. 9) between the two spinous processes, and advanced to reach the anterior portions of the two adjacent spinous processes;

a3) A blunt obturator 76 is inserted over the K-wire 72, and advanced (Fig. 10) to reach the posterior portions of the two adiacent spinous processes;

a4) one or more dilater tubes 80, 81, 82, of increasing diameter, are inserted over the blunt obturator (Fig. 11), and advanced to reach the posterior portions of the two adjacent spinous processes, to obtain a proper diameter for inserting a working sleeve 83;

a5) a working sleeve 83 is introduced over the larger dilater tube;

a6) A trephine 86 is then introduced in the working sleeve 83, after having removed the dilater tubes; trephine 86 is guided by the K-wire (Fig. 12) to reach the zone between the anterior portions of two adjacent spinous processes, and it is actuated to remove tissues from the zone located between the anterior and posterior portions of two adjacent spinous processes, whereby a cavity is created. Sometimes use of a little forceps is required to remove a cylindrical portion of tissues remained in the interspinous space;

b1) After removal of threphine 86 from working sleeve 83, an interspinous process spacer 10 in the collapsed configuration is inserted percutaneously in the cavity created at step a6) by means of a suitable instrument 90, always by penetrating from the back along the sagittal plane of the patient (Fig. 13). Spacer 10 is fixed to instrument 90 as described with reference to Figs. 15-17;

b2) The spacer 10 is positioned in the cavity created at step a6) with the distal end

reaching nearly the anterior portions of two adjacent spinous processes and the proximal end corresponding substantially to the posterior portions of the spinous processes (Fig. 5 and 13);

c1) The spacer is then operated with instrument 90 to effect transition of the arms of the spacer from the collapsed configuration to the extended configuration, in which they engage the adjacent spinous processes to prevent movement of the spacer (Fig. 6, 7 and 14);

c2) The instrument and other tools are removed.

It is pointed out that any step above is performed percutaneously and by operating substantially in the sagittal plane. Also, penetration is performed substantially in the direction of arrow A of Fig. 6 and 8, namely a direction slightly inclined upwardly with respect to the horizontal plane, with the distal end higher than the proximal end of spacer 10. This procedure of insertion minimizes the path through tissues, thereby minimizing exposure to radiation due to a reduced time of fluoroscopic guidance. Also, no cavity is created beyond the point at which the arms of the spacer engage the spinous processes, thus avoiding the risk of injury of the nervous structures in the spinal canal. This is possible since the arms are connected to the distal end of the spacer and are folded in the proximal direction. Deployment of the arms requires a rotation that stops when the arms have reached a vertical position at the distal end of the spacer, so that the method of implantation does not interfere with the region beyond the distal end of the spacer.

Moreover, housing the two pairs of arms in the collapsed configuration within the internal cavity of hollow spacer member 10 prevents the arms from contact with the tissues of the region in which the spacer is inserted before deployment.

In the unlikely event that the spinal implant needs to be removed or repositioned, a reverse procedure can be adopted. The spacer 10 can be transitioned from the extended configuration to the collapsed configuration before removal or repositioning, and the extended configuration can be resumed in case of repositioning.

An embodiment of an instrument for implanting an interspinous process spacer is described with reference to Fig. 15, 16 and 17.

Fig. 15 and 16 show the portion of instrument 90 designed to engage the engaging means 40 of spacer 10 to effect transition from the collapsed state to the extended state. Fig. 17 shows the portion of instrument 90 designed to be actuated by a surgeon. In Figs. 15-16 the end portion of instrument 90 is shown with partially broken parts to better illustrate the internal structure of the instrument.

Starting from the inner part, the instrument 90 comprises a setscrew wrench 92 suitable to be operatively introduced into socket head screw 42 of spacer 10. Setscrew wrench 92 is fixed to a drill member 94 that can be rotated according to arrow B within the body of instrument 90. Such rotation is actuated by turning the portion of drill member handle 94 that projects from the back of the instrument (Fig. 17). Instrument 90 comprises also a first tubular member 91 coaxial and external to setscrew wrench 92, and a second tubular member 93 coaxial and external to first tubular member 91. Tubular member 91 is rotatable around its longitudinal axis. Four shaped projections 96 extend from the end face of first tubular member 91, and two projections 98 extend from the end face of second tubular member 93.

Projections 98 are designed to engage slits 46 on the proximal end 10b of spacer 10, and function as guide elements for coupling the instrument 90 to spacer 10.

Shaped projections 96 are designed to be inserted into slits 44 on the proximal end 10b of spacer 10, and to be rotated after the insertion to hold firmly the spacer on the tip of the instrument 90. Rotation of first tubular member 91 is effected by turning wings 100, which project from the second tubular member 93 through slots 95 (Figs. 13, 14, 17) and can be actuated by a surgeon.

With reference to the step b1) of Fig. 13, the spacer 10 is supported by instrument 90 by inserting projections 96, 98 into slits 44,46 under the guide of projections 98. Also, setscrew wrench 92 is inserted into socket head screw 42. The spacer 10 is then brought to the target position through working sleeve 83. When the target position is reached, setscrew wrench 92 is caused to rotate by turning drill member 94 of instrument 90. The position of spacer 10 is kept fixed by mutual engagement of projections 96, 98 and slits 44,46, while engaging means 40 of spacer 10 are rotated, so that transition to the extended state of the arms of the spacer is effected. Then step c2) is performed.

The spacer 10 can be made from any number of biocompatible materials, metallic or other, such as, for example, stainless steel, titanium, polyetheretherketone (PEEK), carbon fiber, ultra-high molecular weight polyethylene (UHMWPE), and the like. The material of the spacer can have a tensile strength similar to or higher than that of bone. In radiotransparent embodiments, the spacer includes a radiopaque material, such as bismuth, to facilitate tracking the position of the spinal implant during insertion and/or repositioning.

Many modifications and variations of the invention can be made without departing from its spirit and scope, as defined in the appended claims.

CLAIMS

1. Percutaneous interspinous process spacer comprising a spacer member (10) comprising:
   - rotatable arms (20, 22; 24,26) configured to assume a collapsed configuration and an extended configuration;
   - actuation means (30, 32, 34) to effect transition from said collapsed configuration to said extended configuration of said arms (20, 22; 24,26), and vice-versa;
   - engaging means (40) disposed at a proximal portion (10b) of said spacer member, configured to operate said actuation means (30, 32, 34) with an instrument for implanting said interspinous process spacer;

   characterized in that said rotatable arms (20, 22; 24,26) are connected to a distal portion of said spacer member and in said collapsed configuration are folded in a proximal direction;

   whereby said arms are extended by rotation in a distal direction and in said extended configuration are suitable to operatively engage spinous process of a patient to limit movement thereof.
2. Percutaneous interspinous process spacer according to claim 1, characterized in that said spacer member is provided with means to limit rotation of said rotatable arms (20, 22; 24,26) are connected at a distal portion (10a) of said spacer member .
3. Percutaneous interspinous process spacer according to claim 2, characterized in that said rotatable arms (20, 22; 24,26) comprise a first pair of arms (20, 22) and a second pair of arms (24, 26), each pair being fixed to pins (21, 25) rotatably mounted in corresponding holes at a distal portion (10a) of said spacer member (10), whereby said transition from said collapsed configuration to said extended configuration of said arms is effected by rotation of said arms in a distal direction.
4. Percutaneous interspinous process spacer according to claim 2, characterized in that the body of said spacer member (10) is hollow and said rotatable arms (20, 22; 24,26) in said collapsed configuration are contained within the hollow body of said spacer member (10).
5. Percutaneous interspinous process spacer according to claim 2, characterized in that said rotatable arms (20, 22; 24,26) in said extended configuration project from the internal cavity of said hollow spacer member (10) and abut against the distal portion (10a) of said spacer member.
6. Percutaneous interspinous process spacer according to claim 2, characterized in that said

rotatable arms (20, 22; 24,26) in said extended configuration project from the internal cavity of said hollow spacer member (10) and assume a configuration substantially perpendicular to the vertical axis Y of said spacer member (10).

7. Percutaneous interspinous process spacer according to claim 2, characterized in that said rotatable arms (20, 22; 24,26) in said extended configuration project from the internal cavity of said hollow spacer member (10) through vertical slits (14, 16) provided in opposite faces (6, 8) of said spacer member (10).

8. Percutaneous interspinous process spacer according to claim 2 or 3, characterized in that said actuation means (30, 32, 34) to effect rotation of said arms (20, 22; 24, 26) comprise:

- a rod (32) provided with a threaded upper portion (34) and with a lower portion comprising a double rack (30, 33);
- a nut (36) rotatably mounted within the body of said spacer member (10), said nut (36) being provided with an internal thread engaging said threaded upper portion (34) of said rod (32) and being rigidly connected to said engaging means (40);
- gear wheels (23, 27) rigidly connected to said arms (20, 22; 24,26) and operatively coupled to said double rack (30,33) of said rod (32);

whereby rotation of said nut (36) causes rotation of said arms (20, 22; 24,26).

9. Percutaneous interspinous process spacer according to claim 8, characterized in that said arms (20, 22; 24, 26) and said gear wheels (23, 27) are fixed to pins (21,25) rotatably mounted in corresponding holes of said spacer member (10).

10. Percutaneous interspinous process spacer according to claim 8, characterized in that said nut (36) comprises an upper rib (36a) hosted in a corresponding seat in the inner wall (11) of said spacer member (10), whereby sliding within said spacer member (10) is prevented.

11. Percutaneous interspinous process spacer according to claim 2 or 3, characterized in that said engaging means (40) comprise a socket head screw (42) suitable to engage a setscrew wrench, whereby rotation of said engaging means cause said actuation means to effect said transition from said collapsed configuration to said extended configuration of said arms (20, 22; 24,26).

12. Percutaneous interspinous process spacer according to claim 11, characterized in that said engaging means (40) comprise slits (44, 46) on the proximal end (10b) of said spacer member (10), suitable to engage corresponding projections of an instrument for implanting said interspinous process spacer (10).

13. Percutaneous interspinous process spacer according to claim 2, characterized in that at least a portion of said arms (20, 22, 24, 26) has a rough surface to increase gripping to said spinous processes.

14. Percutaneous interspinous process spacer according to claim 2, characterized in that at least a portion of said arms (20, 22, 24, 26) is provided with projections (29), to increase gripping to said spinous processes.

15. Percutaneous interspinous process spacer according to claim 2, characterized in that said first pair of arms (20, 22) and said second pair of arms (24, 26) are symmetrically disposed with respect to a central plane containing said axis (Y) of said spacer member (10), said central plane corresponding to the sagittal plane (S) of a patient's body after implantation of said spacer member (10).

16. Method of implanting a percutaneous interspinous process spacer according to any of claims 1-15, said interspinous process spacer being suitable to effect a transition from a collapsed configuration to an extended configuration, said method comprising the steps of:

a) percutaneously providing a cavity between the anterior and posterior portions of two adiacent spinous processes of a body, said cavity being provided by operating substantially in the sagittal plane;

b) percutaneously inserting an interspinous process spacer in a collapsed configuration, said insertion being performed by operating substantially in the sagittal plane;

c) percutaneously effecting said transition from said collapsed configuration to said extended configuration of said interspinous process spacer by engaging means disposed at a proximal portion of said spacer, configured to engage an instrument for implanting said interspinous process spacer, said instrument being engaged and operated substantially in the sagittal plane, said transition comprising a rotation of the arms of said spacer in a distal direction;

whereby said spacer in said extended configuration operatively engage spinous process of a patient to limit movement thereof.

17. Method according to claim 16, wherein step a) comprises:

a1) inserting a discal needle between two spinous processes (51, 52), under fluoroscopic guidance, by penetrating from the back along the sagittal plane (S) of the patient;

a2) introducing a Kirschner Wire between said spinous processes, and advancing it to

reach the anterior portions of thereof;

a3) inserting a blunt obturator over said Kirschner Wire, and advancing it to reach the posterior portions of said spinous processes;

a4) inserting one or more dilater tubes over said blunt obturator, and advancing them to reach the posterior portions of the two adiacent spinous processes;

a5) a working sleeve 83 is introduced over the larger dilater tube;

a6) introducing a trephine guided by the Kirschner Wire to reach the zone between the anterior portions of two adjacent spinous processes, and actuating it to remove tissues from the zone located between the anterior and posterior portions of two adjacent spinous processes, whereby a cavity is created.

18. Method according to claim 16, wherein step b) comprises:

b1) percutaneously inserting said interspinous process spacer in a collapsed configuration in said cavity created at step a5) by means of a suitable instrument, said insertion being performed by penetrating from the back along the sagittal plane of the patient;

b2) positioning said spacer in said cavity with the distal end reaching substantially the posterior portions of two adjacent spinous processes and the proximal end corresponding substantially to the anterior portions of the spinous processes.

19. Method according to claim 16, wherein step c) comprises:

c1) operating said spacer with an instrument to effect transition of the arms of the spacer from the collapsed configuration to the extended configuration, in which they engage the adjacent spinous processes to prevent movement of the spacer;

c2) removing said instrument and other tools.

20. Instrument (90) for implanting a percutaneous interspinous process spacer (10) according to any of claims 1-15, characterized by comprising means (92, 96, 98) for engaging and supporting said percutaneous interspinous process spacer at the proximal end thereof, and means (92) to effect transition from said collapsed configuration to an extended configuration of said spacer (10).

21. Instrument according to claim 20, characterized in that said means (92, 96, 98) for engaging and supporting said spacer (10) comprise a plurality of projections (96, 98) suitable to be inserted into corresponding slits of said spacer.

22. Instrument according to claim 20, characterized in that said means (92) to effect transition from said collapsed configuration to an extended configuration of said spacer (10) comprise a projecting setscrew wrench (92) to be operatively introduced into a

socket head screw (42) of engaging means (40) of said spacer (10).

23. Instrument according to claim 20, characterized in that said means (92, 96, 98) for engaging and supporting said spacer (10) comprise projections (96) extending from the end face of a first tubular member (91), and projections (98) extending from the end face of a second tubular member (91), said second tubular member (93) being coaxially and rotatably mounted on said first tubular member (91), which is in turn coaxial to said setscrew wrench (92).

24. Instrument according to claim 20, characterized in that said first tubular member (91) is provided with wings (100) projecting through slots (95) of said second tubular member (93), whereby said first tubular member and said projections (98) extending from the end face of a second tubular member (91) are rotated.

25. Kit comprising a percutaneous interspinous process spacer (10) according to any of claims 1-15, an instrument (90) for implanting a percutaneous interspinous process spacer according to any of claims 20-24, and one or more tools according to any of claims 15-18.

26. Kit according to claim 25, characterized in that said tools comprise a discal needle (70), a Kirschner Wire (72), a blunt obturator (76), one or more working sleeves (80, 81, 82, 83), and a trephine (86).

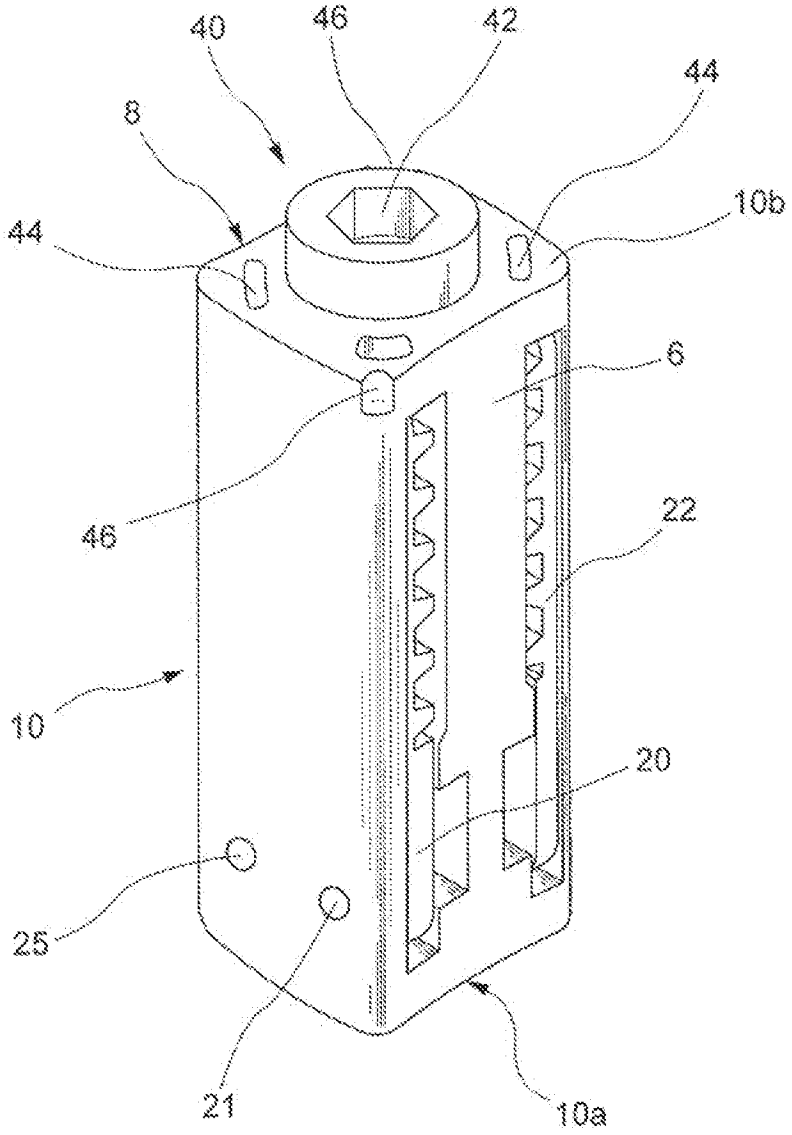


Fig.1

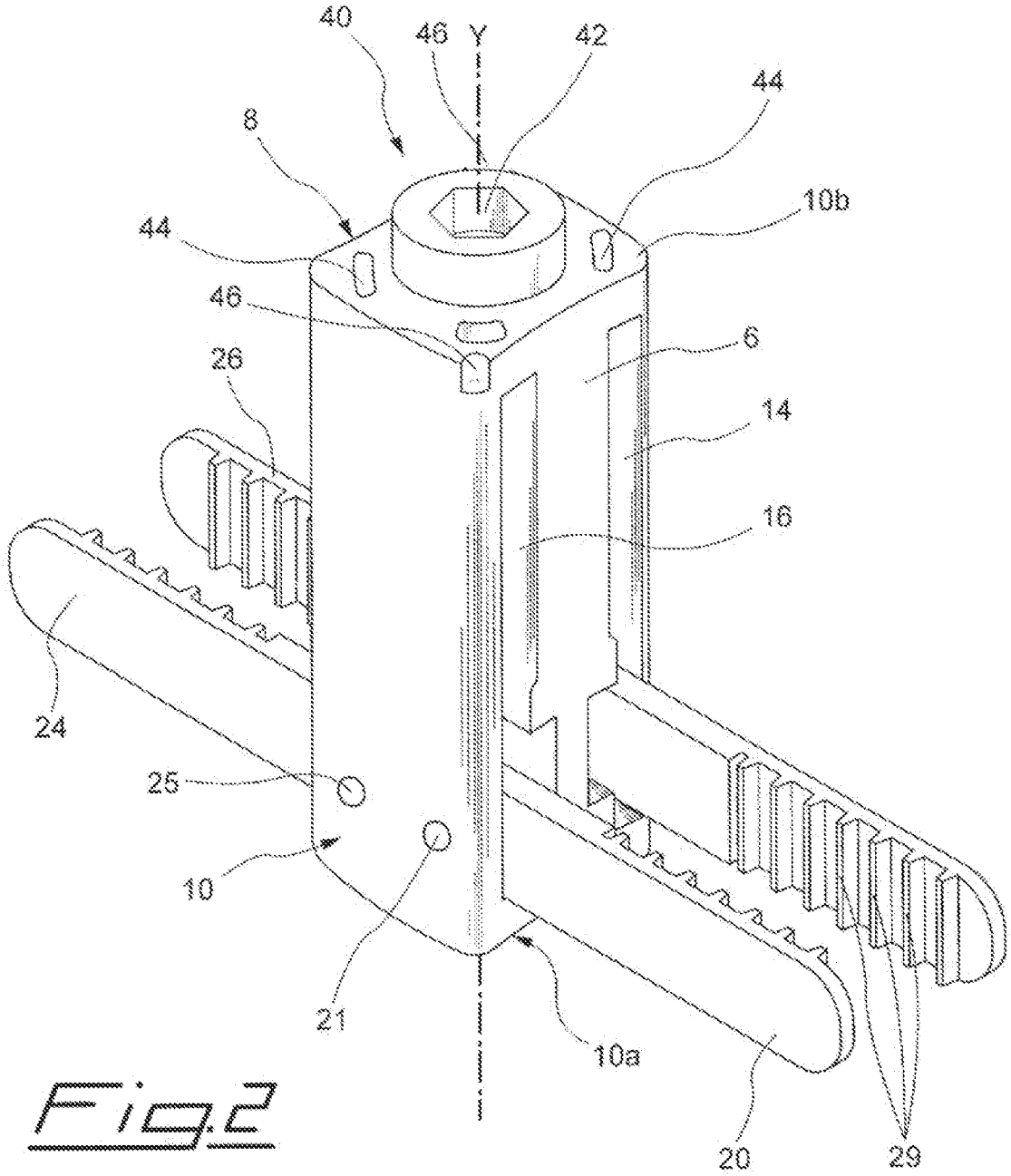


Fig.2

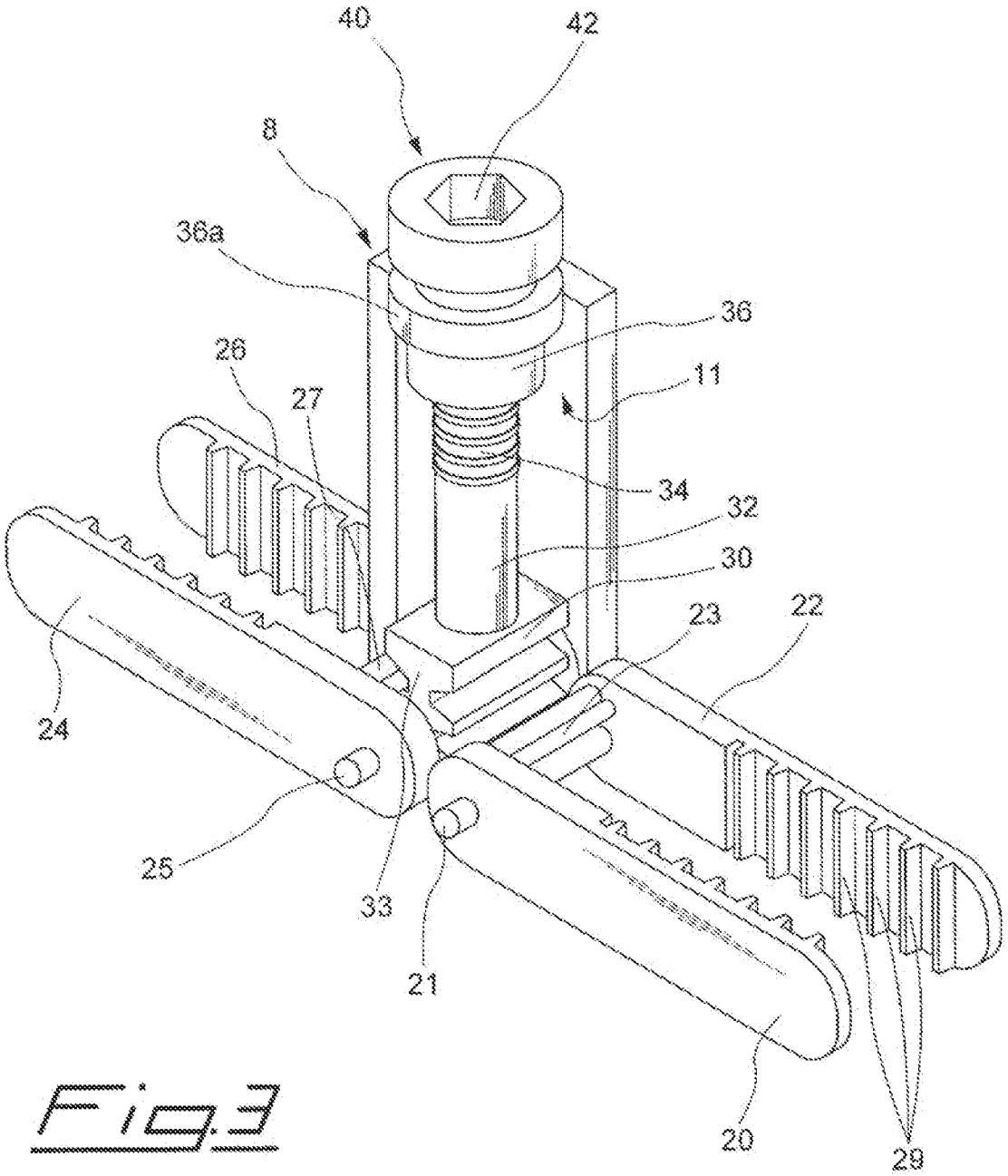


Fig.3

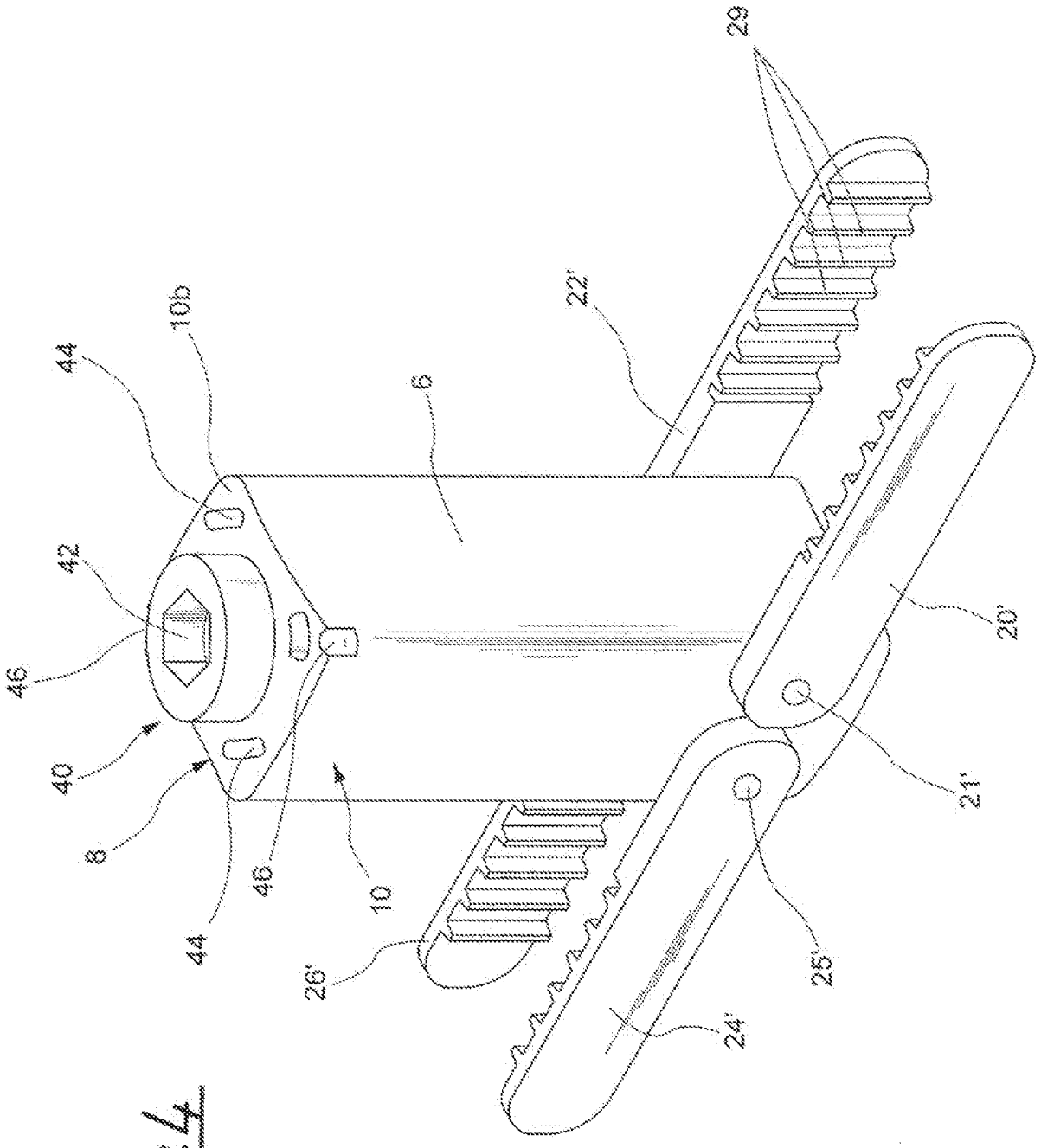


Fig.4

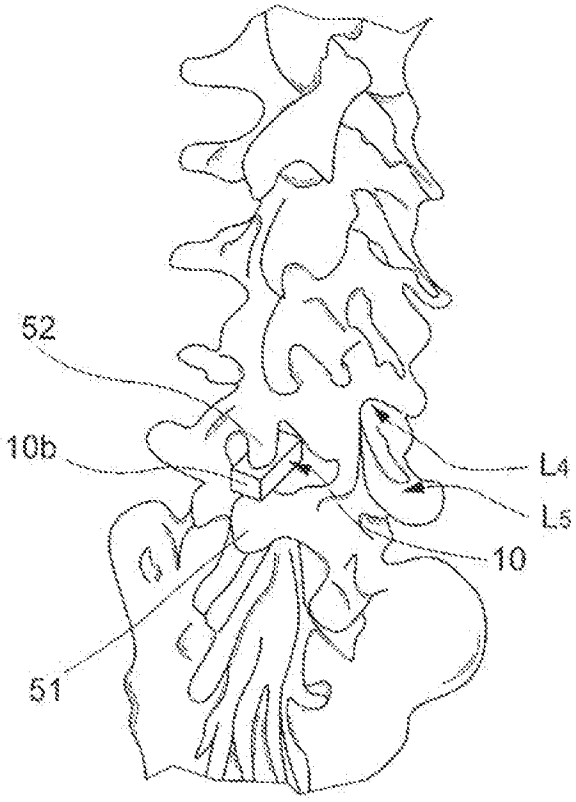
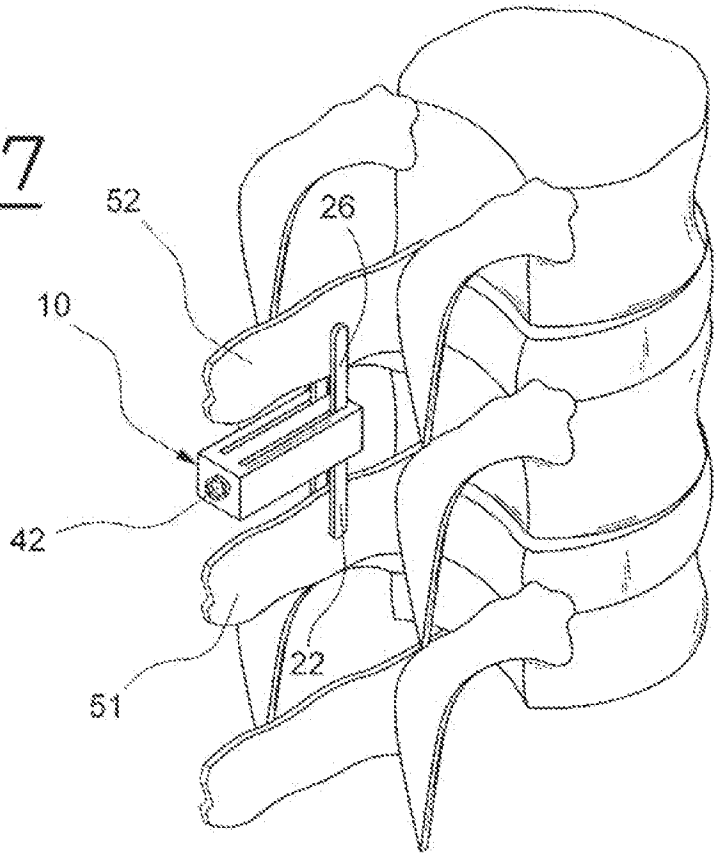


Fig.5

Fig.7



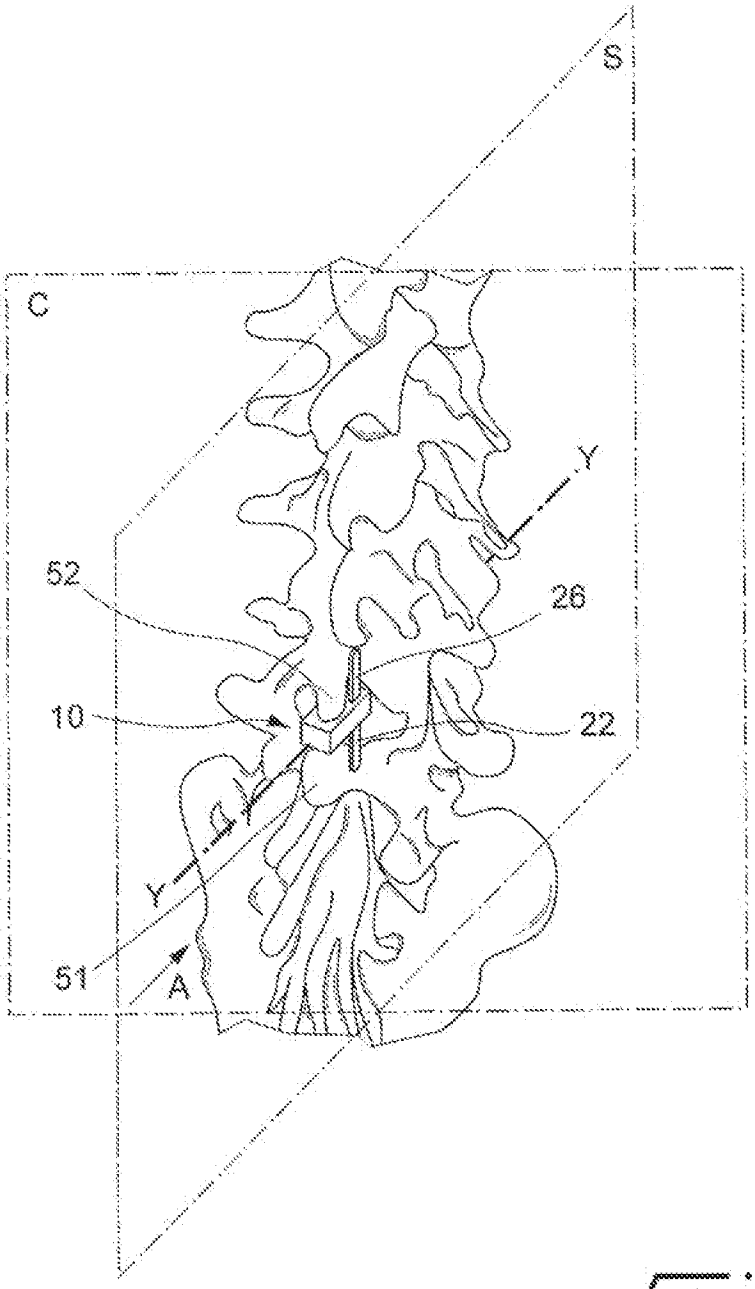


Fig.6

Fig.8

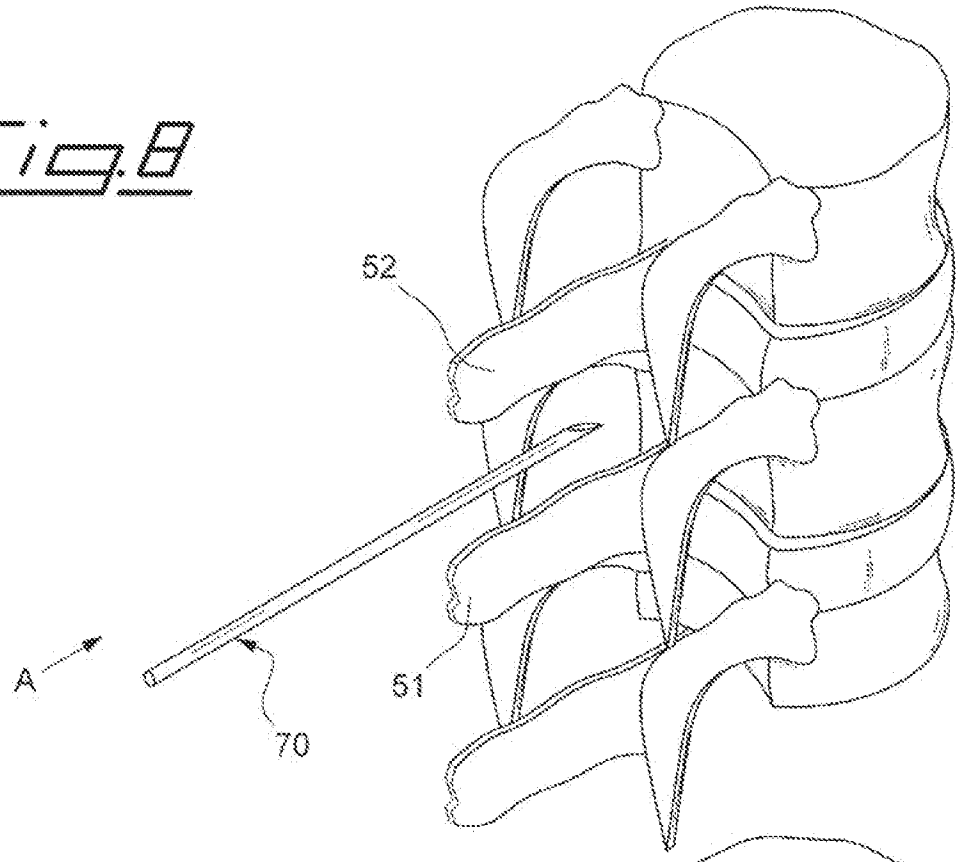


Fig.9

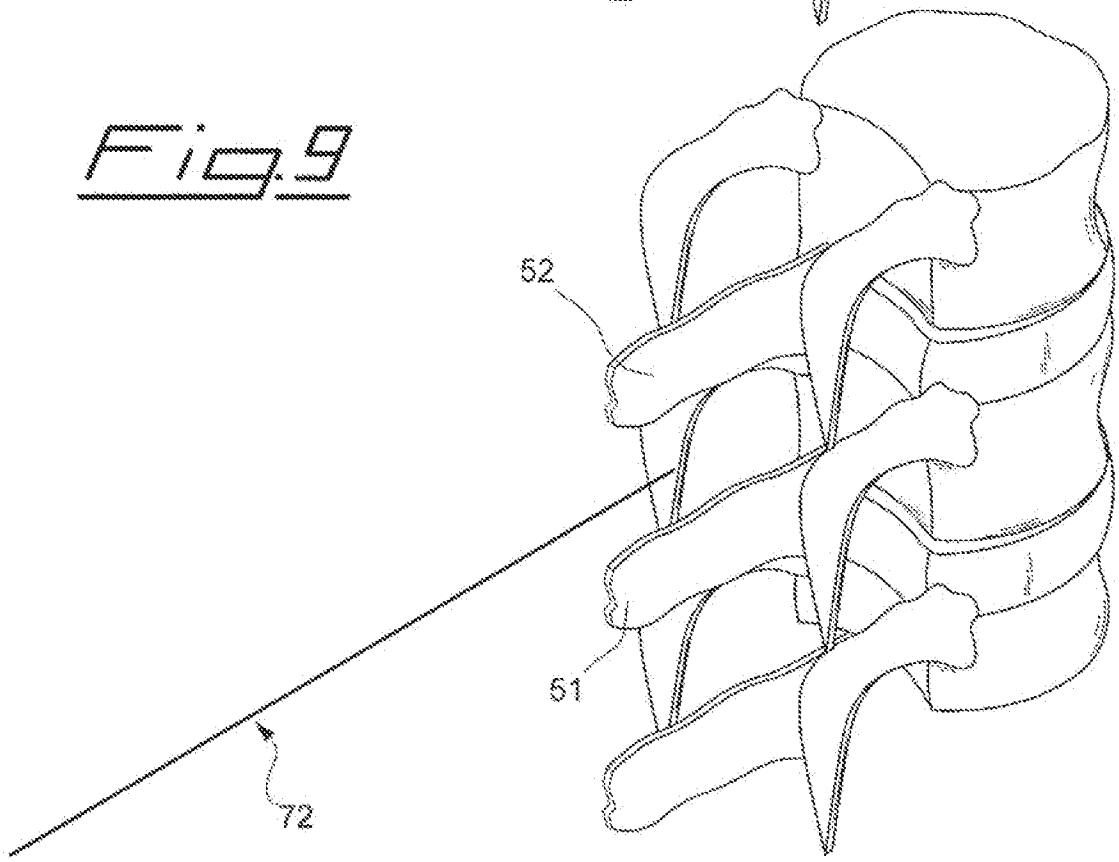


Fig.10

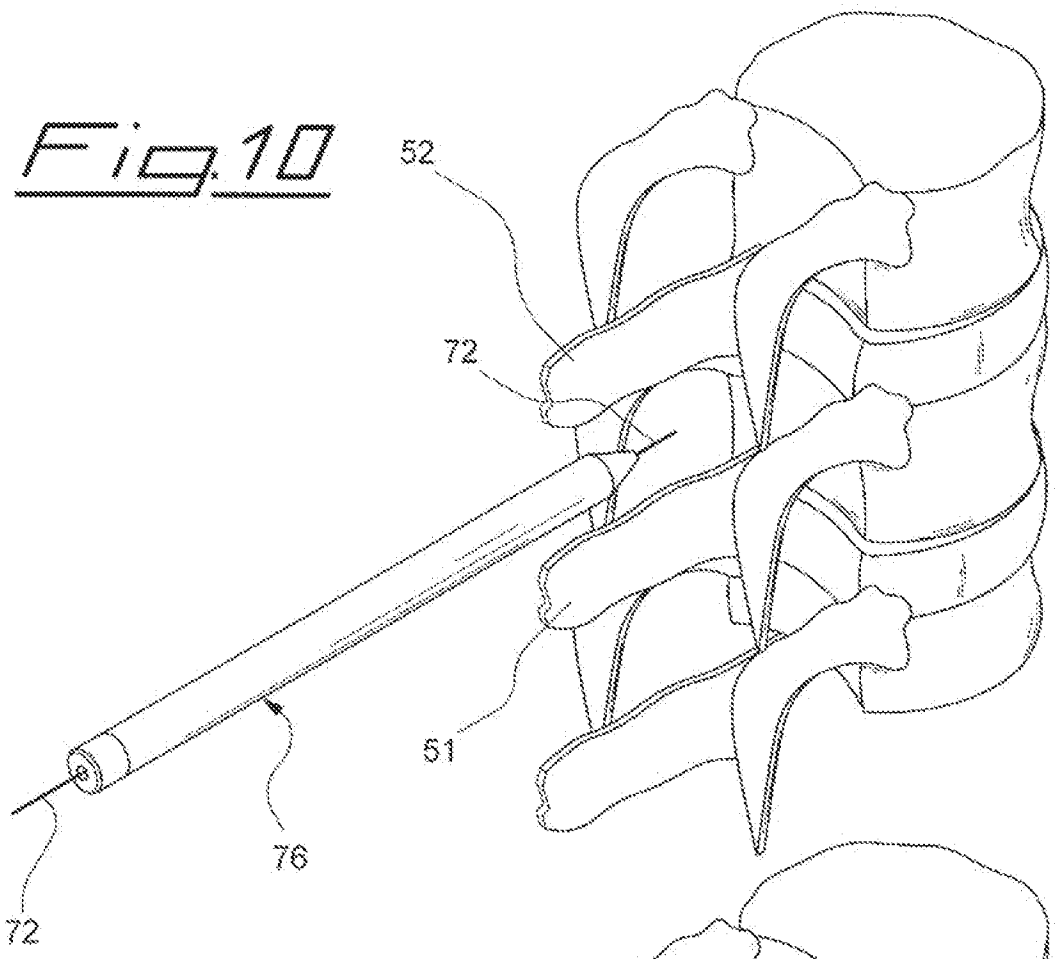


Fig.11

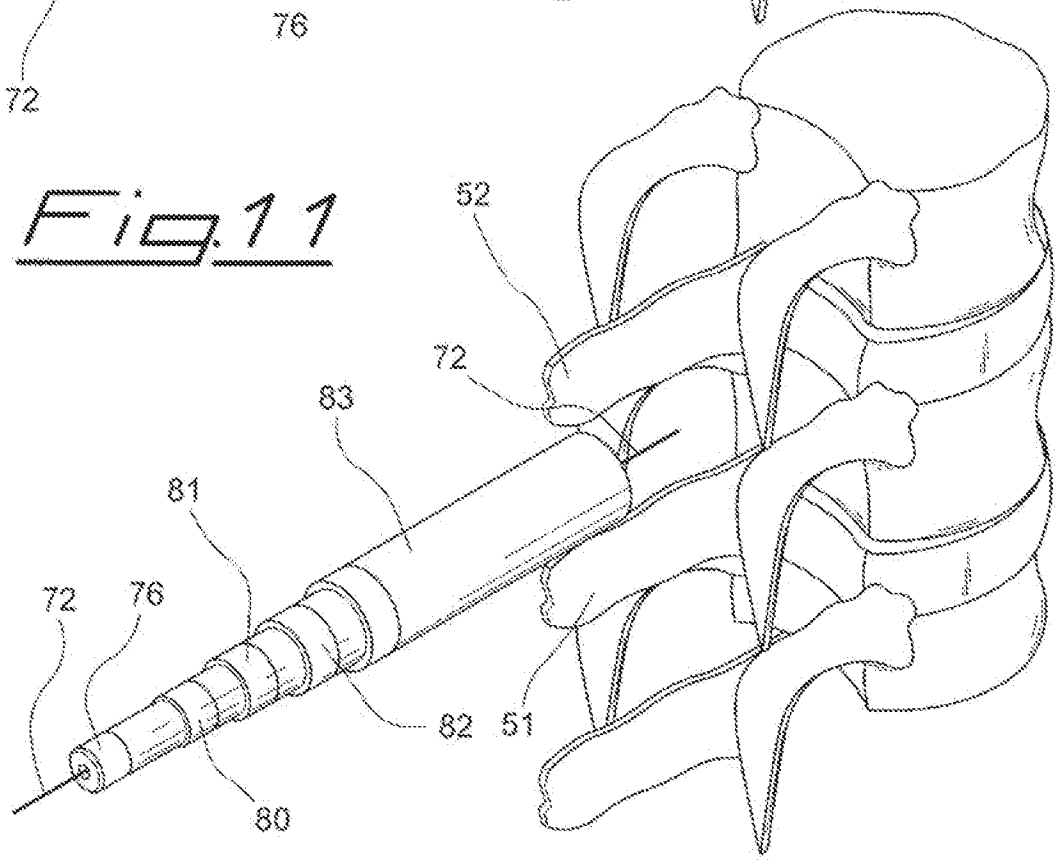


Fig.12

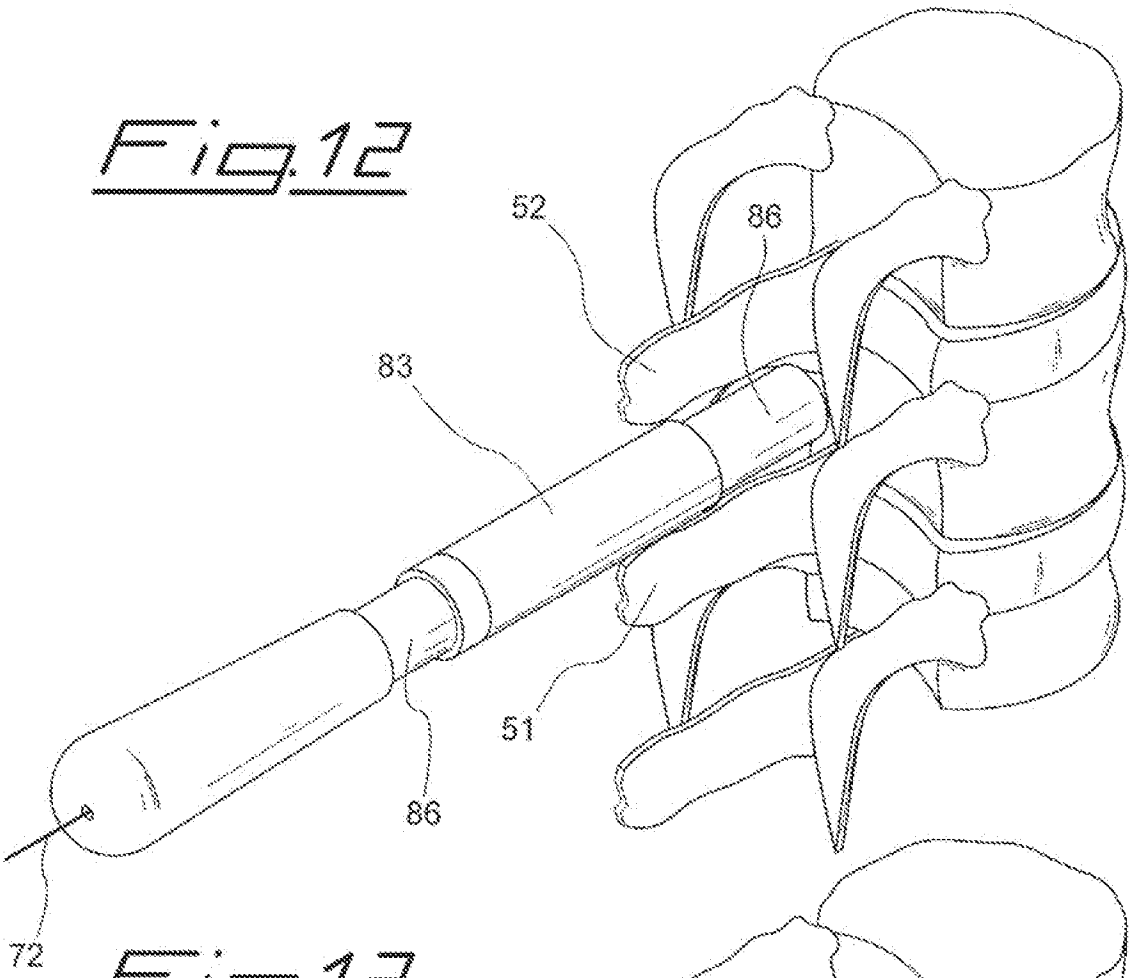
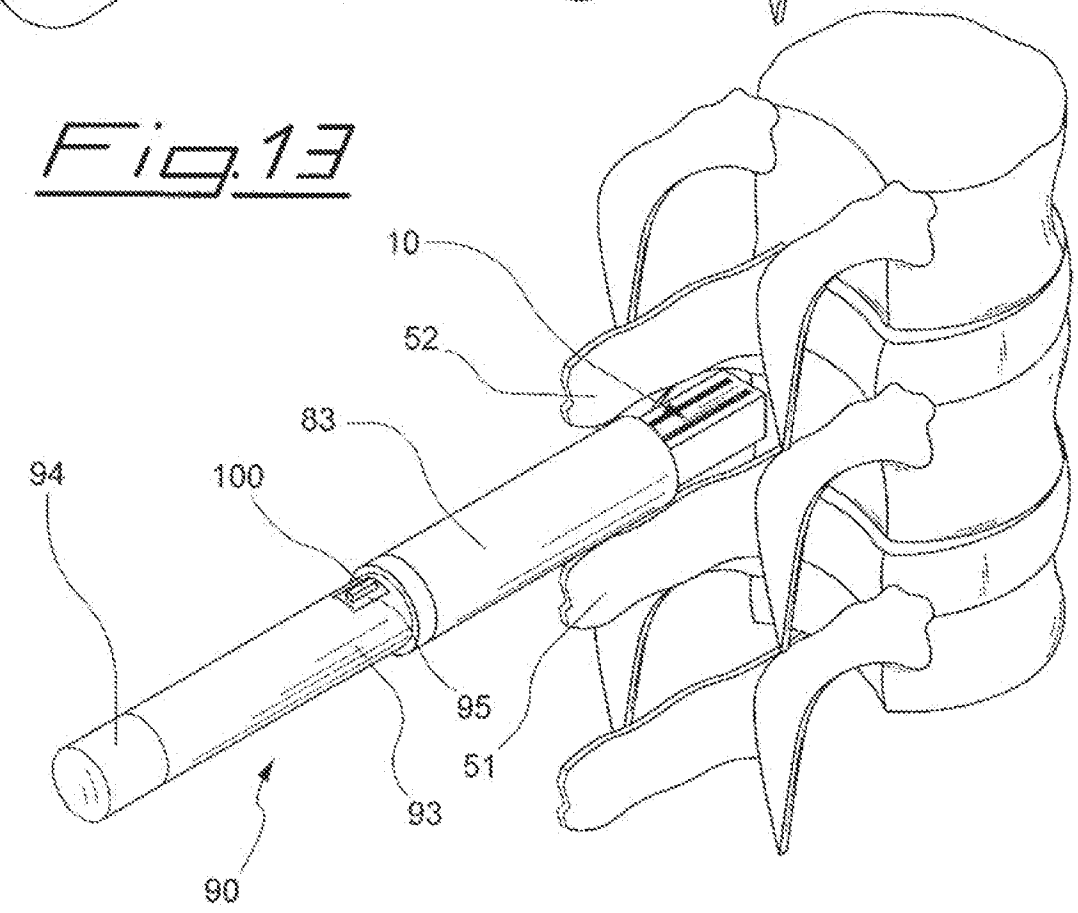


Fig.13



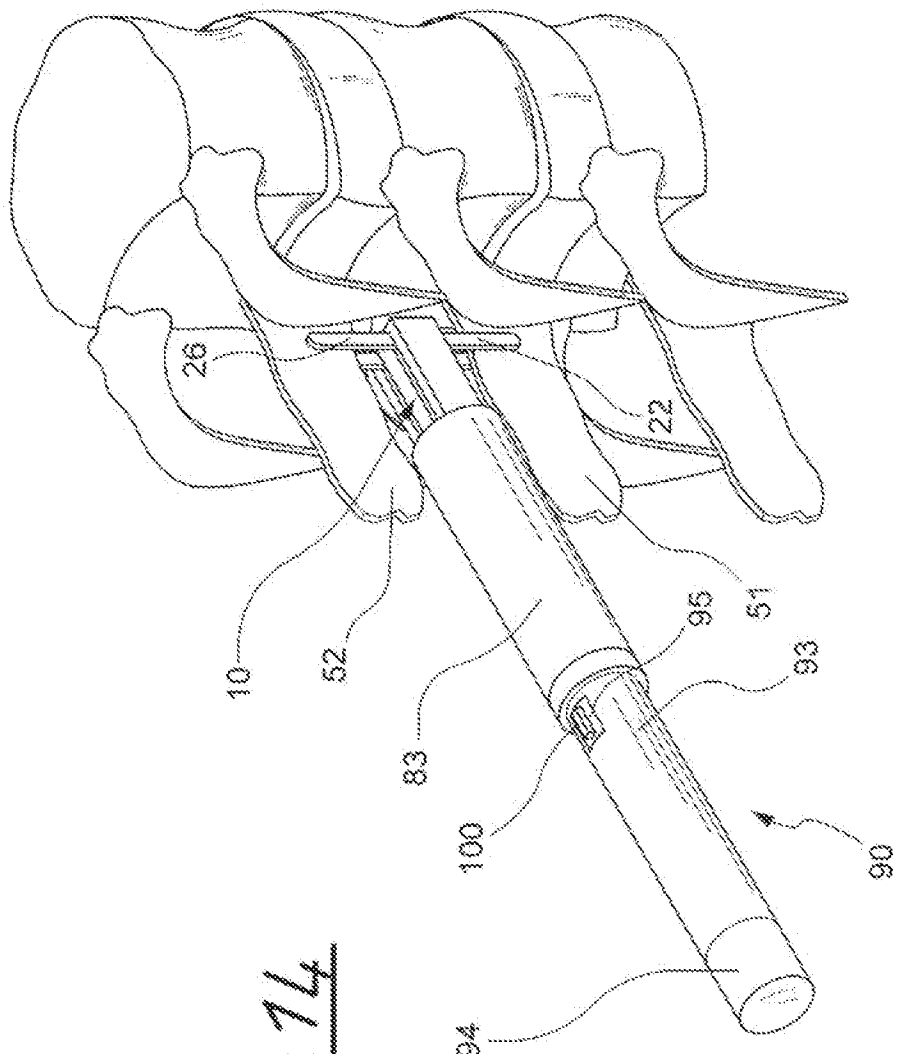


Fig.14

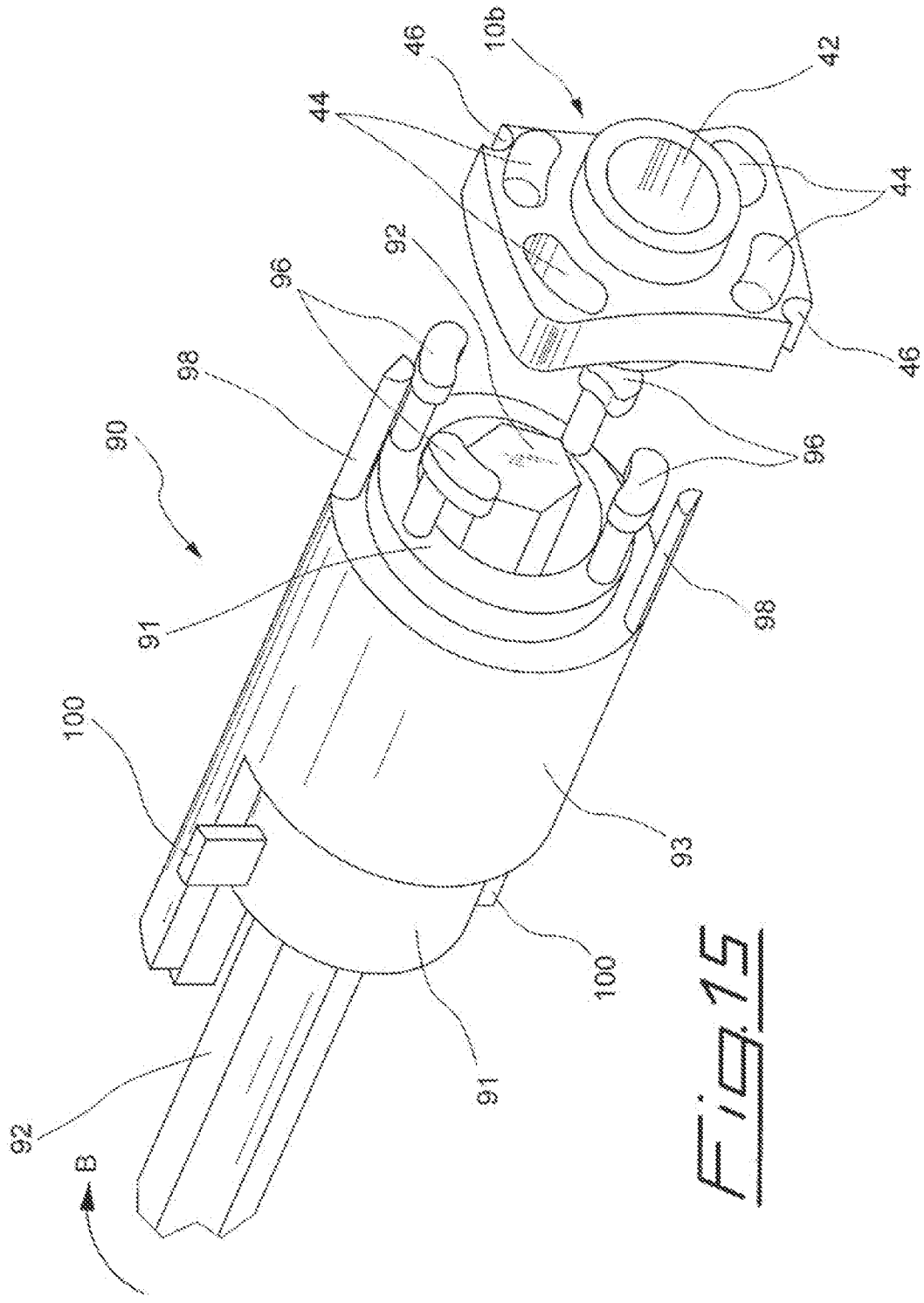


Fig.15

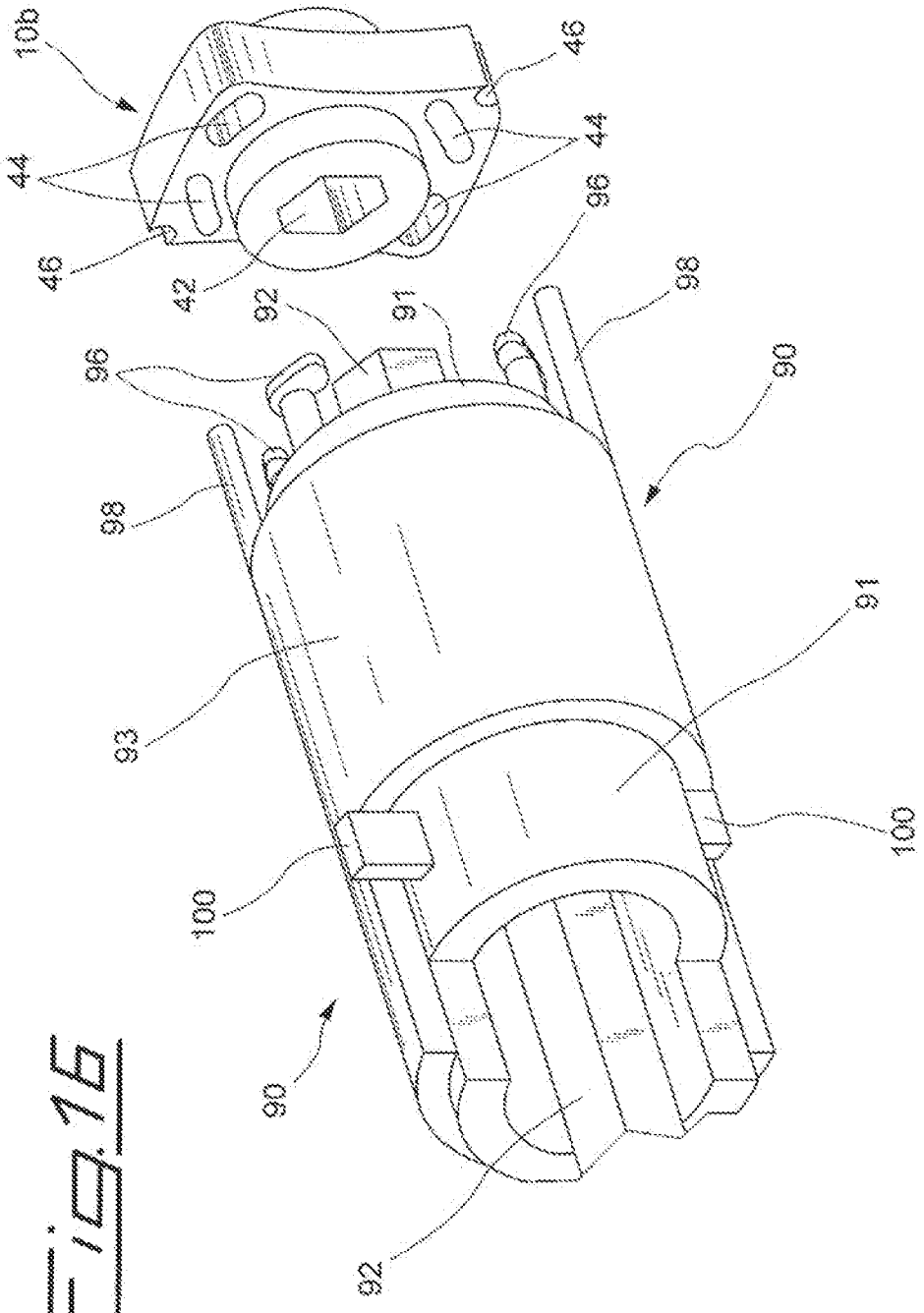


Fig.16

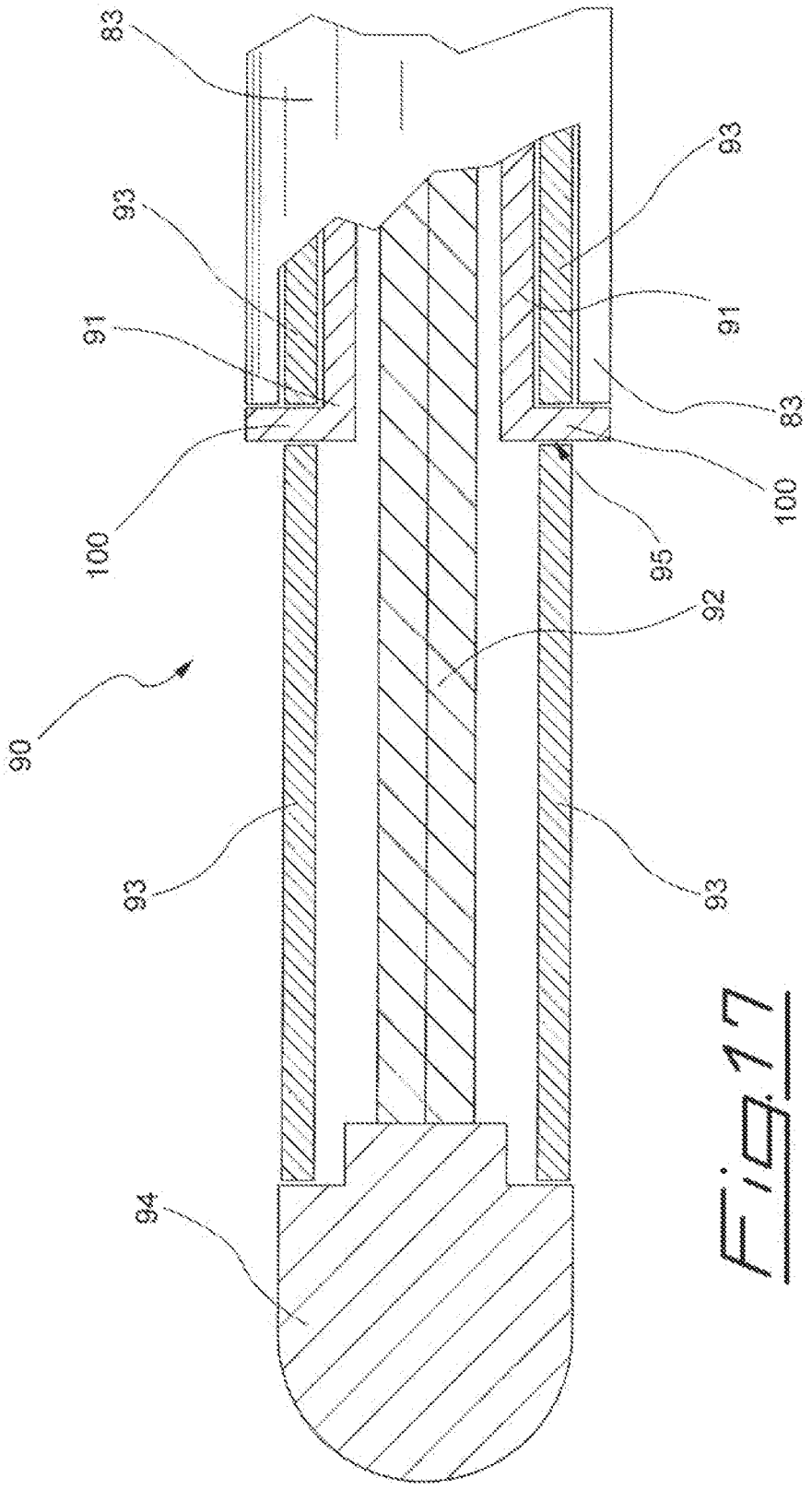


Fig.17

INTERNATIONAL SEARCH REPORT

International application No
PCT/EP2008/068329

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61B17/70
ADD. A61B17/02 A61B17/88

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)
EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2006/264938 A1 (ZUCHERMAN JAMES F [US] ET AL) 23 November 2006 (2006-11-23) figures 11a,11b paragraphs [0022], [0023], [0043], [0044], [0065] - [0068], [0074], [0075], [0077], [0082], [0084]	1-4,6-9, 11,12, 20-22, 25,26
Y		13-15,23
Y	WO 2007/035120 A (LFC SPOLKA Z O O [PL]; CIUPIK LECHOSLAW FRANCISZEK [PL]; GUNZBURG ROBE) 29 March 2007 (2007-03-29) figure 2 page 5, lines 21-24	15

-/--

[X] Further documents are listed in the continuation of Box C. [X] See patent family annex.

* Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
10 March 2009	19/03/2009

Name and mailing address of the ISA/	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Fax: (+31-70) 340-3016	Louka, Maria

Form PCT/ISA/210 (second sheet) (April 2005)

INTERNATIONAL SEARCH REPORT

International application No
PCT/EP2008/068329

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 2005/182416 A1 (LIM ROY [US] ET AL) 18 August 2005 (2005-08-18) paragraph [0021] figure 1 figure 8	13,14,23
X	US 2006/084988 A1 (KIM DANIEL H [US]) 20 April 2006 (2006-04-20) figures 25,28,29 paragraphs [0112], [0118], [0119], [0125]	1,3,5, 20,21,25

INTERNATIONAL SEARCH REPORT

International application No.
PCT/EP2008/068329

Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. [X] Claims Nos.: 16-19
because they relate to subject matter not required to be searched by this Authority, namely:

Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery

2. [ ] Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. [ ] Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. [ ] As all required additional search fees were timely paid by the applicant, this international search report covers allsearchable claims.

2. [ ] As all searchable claims could be searched without effort justifying an additional fees, this Authority did not invite payment of additional fees.

3. [ ] As only some of the required additional search fees were timely paid by the applicant, this international search reportcovers only those claims for which fees were paid, specifically claims Nos.:

4. [ ] No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

[ ] The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.

[ ] The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.

[ ] No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/EP2008/068329

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 2006264938 A1	23-11-2006	AU 2006227185 A1	28-09-2006
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